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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,667	07/28/2000	David Putnam	10436-0010-999	3663

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1627

DATE MAILED: 09/10/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/628,667

Applicant(s)

Putnam et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1627



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30-43 and 126-128 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-43 and 126-128 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5,6,15 6) ☐ Other:

### **DETAILED ACTION**

1. The Response filed June 20, 2002 (Paper No. 14) is acknowledged. No claims were amended, added or cancelled in this response. Therefore, claims 30-43 and 126-128 are pending.

#### ***Election/Restriction***

2. Applicant's election of Group III and election species with traverse (in Papers No. 9 & 14) are acknowledged.
3. With respect to the restriction, applicant has cancelled the claims drawn to all other groups, thus the arguments are moot. Moreover, as stated in the Restriction Requirement, the different methods and products of Groups I – X would require completely different searches in the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden. The requirement is still deemed proper and is therefore made FINAL.
4. With respect to the species, the examiner maintains that the species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

5. Claims 30-43 and 126-128 read on the elected species and are under examination.

6. Please note MPEP § 803.02 with respect to species elections:

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 30-34 and 126 are rejected under 35 U.S.C. 102(b) as being anticipated by Santus et al (US 5,503,843).

Santus et al disclose a method of high-throughput screening of transdermal formulations for their skin permeation (see Example 8 in columns 19-20) reading on the method of instant claim 30 (and claim 32 with respect to “permeability” testing). The “solutions of Rec 15/2739 free base in various enhancer and combination enhancer

systems” reads on the claimed “array of samples” with the “active component” being the Rec 15/2739 and the “additional component” being the various enhancer and combination enhancer systems of the reference, Rec 15/2739 is a pharmaceutical compound, reading on claims 31 and 126. The formulations are tested using a high-throughput screening apparatus (column 19, lines 21-24) that reads on the limitations of instant claim 34 and the data is generated in a Table (reading on the “data set” of claim 33).

9. Claims 30-34, 40, 126 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by Mak et al (US 5,5490,415).

Mak et al disclose a test apparatus for testing diffusion of a drug (see Abstract and Figures). The use of the apparatus of Mak et al (for example, that which is described in column 1, line 1 through column 2, line 40 & column 3, line 59 through column 4, line 10 & claims 22-25 of the reference) reads on the method of instant claim 30 (also claim 32 with respect to “permeability” testing and the system of claim 34). Mak et al also teach the use of their apparatus for solubility testing (reading on instant claims 32 and 127), see column 4, line 30 through column 5, line 3. The apparatus of Mak et al is used for drug testing (i.e. patented claims 22-25); thus, pharmaceutical compounds, reading on claims 31 and 126 are described. Also, the apparatus of the reference has 24 testing sites, reading on instant claim 40.

10. Claims 30, 31, 32, 33, 35, 126 and 128 are rejected under 35 U.S.C. 102(b) as being anticipated by Takai et al (Chem. Pharm. Bull., 1984).

Takai et al disclose a computer optimization technique for determine optimum formulations of griseofulvin (see Abstract). This reads on the instant claim 30 (also claim 32 with respect to "dissolution" testing and the limitations of claims 33 & 35). See pages 1942 – 1943 for the set up of the optimization experiment.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 30-43 and 126-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Santus et al (US 5,503,843) or Mak et al (US 5,5490,415) or Takai et al (Chem. Pharm. Bull., 1984) as set forth above, in view of Stylli et al (US 5,985,214; of record)

The teachings of Santus, Mak and Takai are set forth supra.

The references lack the teaching of the specific numbers or amounts of compounds used in the method.

However, the optimization of such variables was well established in the art of high-throughput testing, see for example, Stylli et al in general and specifically columns 43 – 44 and 48 for teachings of numbers of samples tested, number per day and amounts.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use any of the methods of Santus, Mak or Takai for any number of samples and any amount of active component. One of ordinary skill would have been motivated to do so due in order to test a large number of samples and also optimize the method for the desired particular active ingredient.

#### ***Status of Claims/Conclusion***

14. No claims are allowed.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703)

308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

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16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
September 9, 2002



MAURIE GARCIA BAKER, Ph.D.  
PATENT EXAMINER